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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/754,364

01/08/2004

Mitchell F. Brin

17641 (BOT)

7607

7590

04/13/2005

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/754,364

Applicant(s)

BRIN ET AL.

Examiner

Lora E. Barnhart

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's traverse of the election requirement in the reply filed on 3/22/05 is acknowledged. The traversal is on the ground(s) that if the examiner finds no art on the elected species (in this case, botulinum toxin type A), the search should be extended to include all seven species. This is not found persuasive because the examiner indeed found art rendering the use of the elected species anticipated and/or obvious. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the arguments were not found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Specification

In the first Office action mailed 1/24/05, the examiner objected to the abstract for having improper content, language, and format (p. 3). The examiner also objected to the improper recitation of trademarks in the specification (p. 4). Finally, The examiner objected to the applicants' presentation of prophetic (simulated) examples in the present tense (p. 4). None of these objections was addressed in the amendment filed 3/22/05, and they are therefore upheld on this Office action.

Double Patenting

The amendment to the claims received 3/22/05 obviates the nonstatutory obviousness-type double patenting rejection over U.S. '544 made in the first Office action. This rejection is therefore withdrawn at this time.

Claim Rejections - 35 USC §§ 112 and 102

Applicant's arguments, filed 3/22/05, with respect to the rejections under 35 U.S.C. §§ 102 and 112 of claims 1-4 have been fully considered and are persuasive. Said rejections of claims 1-4 have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '544 taken in view of U.S. '376 (both cited in prior action).

The applied '544 reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned

by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The claims are drawn to methods comprising the step of locally administering botulinum toxin type A to a graft. In some claims, the botulinum toxin is injected into the wall of a graft blood vessel.

U.S. '544 teaches injection of botulinum toxin type A directly into an artery wall (Examples 1-6). U.S. '544 does not specifically teach injecting botulinum toxin into a grafted vessel but does state that said injection prevents restenosis in a blood vessel (column 7, lines 1-7). U.S. '544 also teaches that its method is applicable to "any blood vessel in the body" (column 9, lines 57-62) and teaches theories of the action of botulinum toxin and application of said action to blood vessels (column 10, line 11, through column 11, line 42). U.S. '544 also teaches that botulinum toxin type A "may be allowed to dilate the blood vessel and/or prevent inflammation of the blood vessel before a procedure is begun" (column 15, line 64, through column 16, line 3).

While applicants argue that the procedure of U.S. '544 is limited to use of balloons, springs, and expanding devices for angioplasty (p. 5, paragraph 1, referring presumably to column 6, lines 41-51 of U.S. '544), U.S. '544 clearly states that these devices comprise only one embodiment of the invention. The method of U.S. '544 may be broadly applied to any "mammal that is having or has had a cardiovascular procedure" (column 6, lines 19-30). U.S. '376 is cited as evidence that one example of such a procedure is an autogenous saphenous vein graft (column 1, lines 30-36).

A person of ordinary skill in the art would have had a reasonable expectation of success in preventing stenosis and reducing inflammation at the site of a grafted blood vessel using the injection of botulinum toxin type A as taught by U.S. '544 because U.S. '544 teaches that said toxin is known in the art to reduce inflammation and to prevent spasm in muscular structures, such as blood vessels (column 2, lines 52-65 and column 15, line 64, through column 16, line 3). The skilled artisan would have been motivated to inject the wall of a blood vessel graft with botulinum toxin type A as taught by U.S. '544 for the expected benefit of preventing said graft from collapsing either before or after implantation (U.S. '544, column 6, lines 24-25).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to administer botulinum toxin type A to a blood vessel graft because U.S. '544 teaches that said administration is useful for preventing stenosis and inflammation in any kind of artery (column 9, lines 57-62).

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

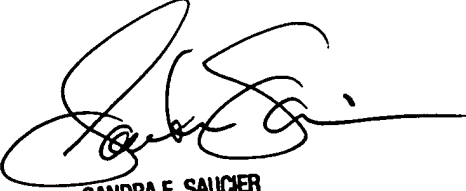
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E Barnhart, whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn, can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart



SANDRA E. SAUCIER
PRIMARY EXAMINER